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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,518	03/16/2004	Donald J. Pinto	PH 7466 NP	3204
23914	7590	02/09/2006	EXAMINER	
LOUIS J. WILLE BRISTOL-MYERS SQUIBB COMPANY PATENT DEPARTMENT P O BOX 4000 PRINCETON, NJ 08543-4000			FREISTEIN, ANDREW B	
		ART UNIT	PAPER NUMBER	
		1626		
DATE MAILED: 02/09/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/801,518	PINTO ET AL.
	Examiner	Art Unit
	Andrew B. Freistein	1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 08 December 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 18-21 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-7 and 9-14 is/are rejected.
- 7) Claim(s) 1-17 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/04/2004.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION

Claims 1-21 are currently pending in the instant application.

Priority

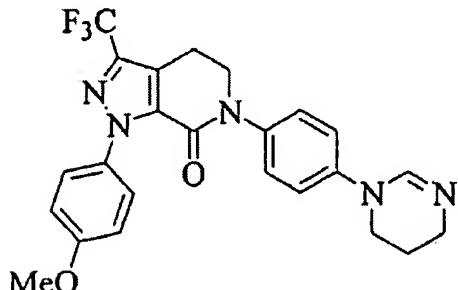
This application claims benefit from US Provisional Application No. 60/455,709, filed 03/18/2003.

Information Disclosure Statement

Applicant's information disclosure statements (IDS), filed on 10/04/2004 and 05/26/2004, have been considered. Please refer to Applicant's copies of the 1449 submitted herewith.

Restriction Requirement

Applicant's election of Group I, claims 1-8 and 17-21, and the species



, in the reply filed on 12/08/2005 is acknowledged.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

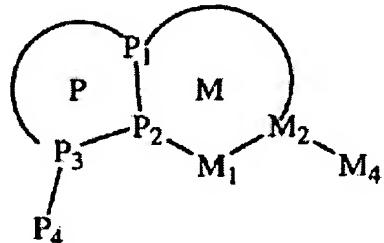
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 and 9-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is drawn to a compound of the formula (I), $P_4-P-M-M_4$, wherein M is a 3-10-membered carbocycle or a 4-10-membered heterocycle consisting of: carbon atoms and 1-3 heteroatoms selected from O, S(O)_p, N, and NZ².

The definitions of P_4 , P, M and M_4 , are so broad that they are indefinite, unsearchable, and unclassifiable. There is no clear unambiguous claim to indicate how the variables are bonded to each other and what rings are in each compound. According to the STN search report, there are over 750,000 projected answers for this core structure and no proper search can be performed (see STN International, Columbus, OH, search performed 01/10/2006).

Similarly, claim 2-7 and 9-14 are indefinite for the same reasons as claim 1. For



example, claim 2 is drawn to a formula , wherein ring M, including P_1 , P_2 , M_1 and M_2 is a 5, 6, or 7 membered carbocycle or a 5, 6, or 7 membered heterocycle. Claim 3 is drawn to 105 different structures for variable M and 44 different structures for variable P. Thus all of claims 1-7 and 9-15 contain widely divergent variables, which creates unsearchable claims.

The claims are unclassifiable, because the variables P_4 , P, M and M_4 , do not indicate a specific ring. For example, compounds containing six-membered hetero rings having two or more heteroatoms of which at least one is N is classified in class 544; compounds containing six-membered hetero rings consisting of one N and five carbon atoms is classified in class 544; and five-membered hetero rings having at least one N atom are classified in class 548. Since the definitions of the variables P_4 , P, M and M_4 define rings of 3-10 members with 0-3 heteroatoms, no proper classification of the compounds of the instant application can be made.

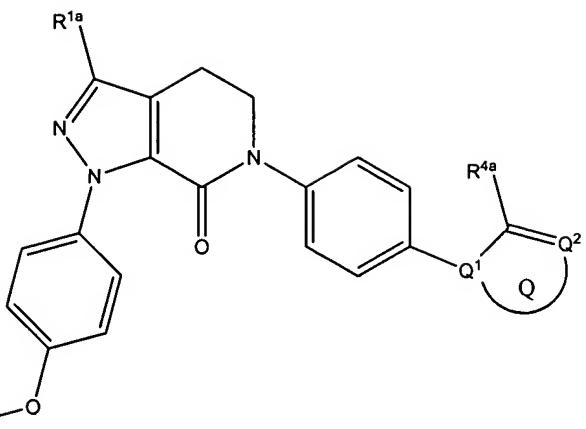
Further, since no proper classification can be made, no prior art search of the class and subclass of claims 1-7 and 9-15 can be made. Therefore, the claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. See MPEP 903.07 and 904 (classification and search).

Status of the Claims

Claims 1-17 (in part) are withdrawn from further consideration by the Examiner as being drawn to non-elected inventions under 37 CFR § 1.142(b). The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and element and would require separate search considerations. In addition, a reference that anticipates one invention would not render obvious the other invention.

Elected and Examined Subject Matter

The scope of the invention of the elected subject matter and the examined subject matter is as follows:



Compounds of the formula $\text{R}-\text{O}$, wherein:

Q¹ is as defined in claim 1;

Q^2 is as defined in claim 1;

Q is as defined in claim 1;

R is as defined in claim 1;

R^{1a} is as defined in claim 1; and

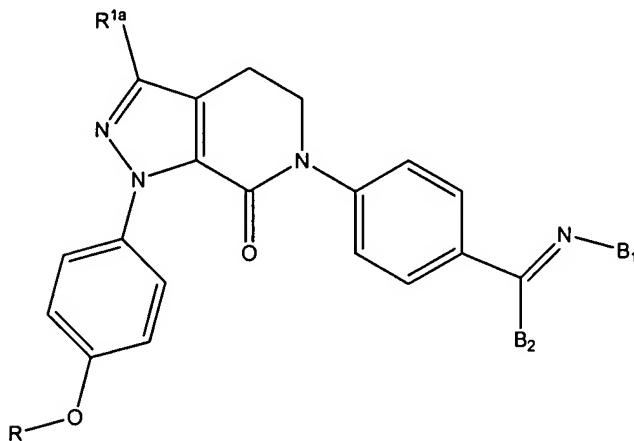
R^{4a} is as defined in claim 1.

Non-elected and Non-examined Subject Matter

The scope of the invention of the non-elected and non-examined subject matter

is as follows:

All compounds of the Formula (I), P₄-P-M-M₄, that are not provided above and more specifically, compounds of the formula



, wherein:

B¹ and **B**² are as defined in claim 1.

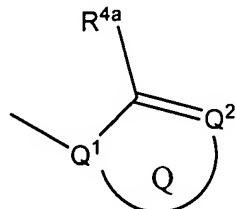
As a result of the election and the corresponding scope of the invention, identified supra, the remaining subject matter of Claims 1-17 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to non-elected inventions. The withdrawn compounds contain varying functional groups such as thiazolidine, piperazine, quinoline, thiophene, morpholine, oxazol, pyran, etc. which are chemically recognized to differ in structure, function, and reactivity.

Therefore, the subject matter which was withdrawn from consideration as being non-elected subject matter materially differs in structure and composition from the elected/examined subject matter so that a reference which anticipates the elected/examined subject matter would not render obvious the non-elected subject matter.

Double Patenting

The Inventors of the instant application have many patents and copending applications with a similar core structure. However, Examiner finds no Double Patenting issues with respect to the scope of the elected invention as defined above.

The closest relevant art with respect to double patenting is US Pat. No. 6,750,225. This patent differs from the instant application because the instant



application claims the variable "B" to represent: , which is a heterocycle with at least one N atom and one double bond in the ring. However, US Pat. No. 6,750,225 claims a compound with pyridine or imidazole, which are Nitrogen-containing heterocycles with two and three double bonds respectively. Thus, the patent claims different compounds.

Closest Relevant Art

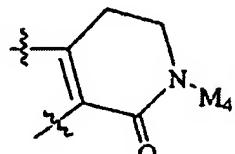
The closest relevant art is Fevig et al. (WO 00/39131), which would be considered prior art under 35 USC 102(b) of non-elected subject matter.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

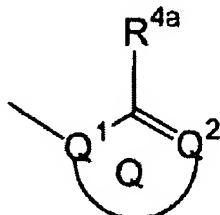
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 of the instant application are drawn to a compound of formula I, P₄-P-



M-M₄, wherein M is

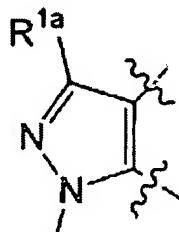
; M₄ is Z-A-B; Z is a bond; A is C₆-carbocycle,



substituted with 0-2 R⁴; R⁴ is F; B is

; Q¹ and Q² are each N; Q is a 5-

membered heterocycle; R^{4a} is C₁alkyl or (CR³R^{3a})_rNR²R^{2a}; R³ and R^{3a} are H; r is 1; and



R² and R^{2a} are each C₁alkyl; P is

; R^{1a} is (CR³R^{3a})_rR^{1b}; r is 0; R^{1b} is

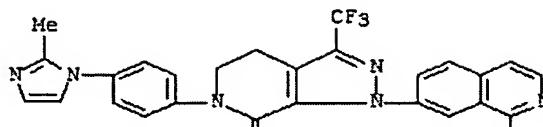


(CF₂)_rCF₃; r is 0; P₄ is G₁-G; G₁ is absent; G is Formula IIa,

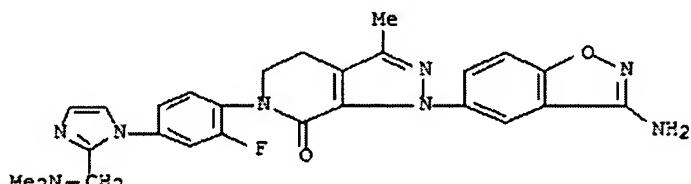
phenyl; D is a six-membered heterocyclic ring consisting of carbon atoms, and 0-2

heteroatoms selected from N and O, which is substituted with R; and R is NH₂.

Claim 17 is drawn to a pharmaceutical composition comprising a therapeutically effective amount of a compound of Formula (I) and a pharmaceutically acceptable carrier.



Fevig et al. disclose the compounds:



(see Fevig, et al, STN International

(2006) HCPLUS Database, Columbus, OH, Accession No. 2000:457072, Reg. Nos. 280119-13-3 and 280119-14-4).

Fevig et al. disclose pharmaceutical compositions comprising the compounds disclosed (see US 6,413,980, col. 216, line 54 – col. 220, line 22).

Claim Objections

Claims 1-17 are objected to as containing non-elected subject matter.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew B. Freistein whose telephone number is (571) 272-8515. The examiner can normally be reached Monday-Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph M^cKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

Andrew B. Freistein
Patent Examiner, AU 1626



Joseph K. McKane
Supervisory Patent Examiner, AU 1626
Date: February 3, 2006